

DEC 10 2007



| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |   |   |   |   |   |   | ATTY. DOCKET NO.: 200.1102CP2 |                               | SERIAL NO.: 09/992,936 |          |                            |    |
|---|----|---|---|---|---|---|---|---|-------------------------------|-------------------------------|------------------------|----------|----------------------------|----|
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary)   |    |   |   |   |   |   |   |   |                               | APPLICANT(S): Robert F. KAIKO |                        |          |                            |    |
|   |    |   |   |   |   |   |   |   |                               | FILING DATE: November 5, 2001 |                        |          | GROUP: 1618                |    |
| U.S. PATENT DOCUMENTS   |    |   |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
| *EXAMINER INITIAL   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                          | NAME                          | CLASS                  | SUBCLASS | FILING DATE IF APPROPRIATE |    |
| /ZF/  | AA | 4   | 7 | 2 | 2 | 9 | 2 | 8 | 02/02/1998                    | BOSWELL et al.                | 514                    | 282      |                            |    |
|   | AB | 3   | 9 | 1 | 6 | 8 | 8 | 9 | 11/04/1975                    | RUSSELL et al.                | 128                    | 145.8    |                            |    |
|   | AC | 6   | 3 | 1 | 0 | 0 | 7 | 2 | 10/2001                       | SMITH et al.                  | 514                    | 282      |                            |    |
|   | AD | 6   | 7 | 6 | 5 | 0 | 1 | 0 | 07/2004                       | CRAIN et al.                  | 514                    | 282      |                            |    |
|   | AE | 4   | 6 | 4 | 4 | 9 | 1 | 0 | 07/04/1989                    | LESLIE et al.                 | 424                    | 494      |                            |    |
|   | AF | 5   | 5 | 8 | 0 | 5 | 7 | 8 | 12/03/1996                    | OSHLACK et al.                | 424                    | 465      |                            |    |
|   | AG | 3   | 1 | 3 | 3 | 1 | 3 | 2 | 05/12/1964                    | LOEB et al.                   | 264                    | 49       |                            |    |
|   | AH | 3   | 1 | 7 | 3 | 8 | 7 | 6 | 03/16/1965                    | ZOBRIST et al.                | 252                    | 137      |                            |    |
|   | AI | 3   | 2 | 7 | 6 | 5 | 8 | 6 | 10/04/1966                    | ROSAEN et al.                 | 210                    | 90       |                            |    |
|   | AJ | 4   | 2 | 8 | 5 | 9 | 8 | 7 | 08/25/1981                    | AYER et al.                   | 427                    | 3        |                            |    |
|   | AK | 4   | 2 | 0 | 0 | 0 | 9 | 8 | 04/29/1980                    | AYER et al.                   | 128                    | 260      |                            |    |
| ↓   | AL | 5   | 4 | 7 | 4 | 9 | 9 | 5 | 12/12/1995                    | DUCHARME et al                | 514                    | 241      |                            |    |
| FOREIGN PATENT DOCUMENTS  |    |   |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
|   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                          | COUNTRY                       | CLASS                  | SUBCLASS | TRANSLATION                |    |
|   |    |   |   |   |   |   |   |   |                               |                               |                        |          | YES                        | NO |
| /ZF/  | AM | 9   | 9 | 3 | 2 | 1 | 2 | 0 | 07/01/1999                    | WO                            | A61K                   | 31/485   |                            |    |
|   | AN | 0   | 6 | 4 | 7 | 4 | 4 | 8 | 04/12/1995                    | EP                            | A61K                   | 31/485   |                            |    |
|   | AO | 9   | 8 | 2 | 5 | 6 | 1 | 3 | 06/18/1998                    | WO                            | A61K                   | 31/485   |                            |    |
| ↓   | AP | 0   | 0 | 3 | 8 | 6 | 4 | 9 | 07/06/2000                    | WO                            | A61K                   | 9/00     |                            |    |
| ↓   | AQ | 0   | 1 | 5 | 8 | 4 | 7 | 7 | 08/16/2001                    | WO                            | A61K                   | 39/00    |                            |    |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |   |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
| /ZF/  | AR | RON MEDZON, MD, "Naltrexone and Nalmefene," Clinical Toxicology Review, Vol. 19, No. 3, December 1996.  |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
|   | AS | Physician's Desk Reference (2001) see Revia, pp. 1146-1149 and Oxycontin, pp. 2697-2701.  |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
|   | AT | Wilmington, Del., PR Newswire; "New Data Published Describing Favorable Safety Profile of REVIA (Naltrexone Hydrochloride Tablets) When Used to Treat Alcohol Dependence," December 1997. |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
| ↓   | AU | Talwin NX, Physician's Desk Reference 48 <sup>th</sup> Edition (1994) Montvale, NJ 2120-2121.   |   |   |   |   |   |   |                               |                               |                        |          |                            |    |
| EXAMINER /Zohreh Fay/ (05/23/2009)  |    |   |   |   |   |   |   |   |                               | DATE CONSIDERED               |                        |          |                            |    |
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /ZF/

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| U.S. PATENT DOCUMENTS   |    |  |    |    |    |   |             |                 |                               |                  |                        |          |                            |    |
| *EXAMINER INITIAL   |    | DOCUMENT NUMBER  |    |    |    |   |             |                 | DATE                          | NAME             | CLASS                  | SUBCLASS | FILING DATE IF APPROPRIATE |    |
| /ZF/  | BA | 4  | 1  | 6  | 0  | 0 | 2           | 0               | 07/03/1979                    | AYER et al.      | 424                    | 15       |                            |    |
|   | BB | 3  | 5  | 4  | 1  | 0 | 0           | 5               | 11/17/1970                    | STRATHMANN et al | 210                    | 19       |                            |    |
|   | BC | 3  | 5  | 4  | 1  | 0 | 0           | 6               | 11/17/1970                    | BIXLER et al     | 210                    | 23       |                            |    |
|   | BD | 6  | 0  | 9  | 6  | 7 | 5           | 6               | 08/01/2000                    | CRAIN et al      | 514                    | 282      |                            |    |
|   | BE | 6  | 3  | 6  | 2  | 1 | 9           | 4               | 03/26/2002                    | CRAIN et al      | 514                    | 285      |                            |    |
|   | BF | 6  | 3  | 9  | 5  | 7 | 0           | 5               | 05/28/2002                    | CRAIN et al      | 514                    | 2        |                            |    |
|   | BG | 20   | 01 | 00 | 06 | 9 | 6           | 7               | 07/05/2001                    | CRAIN et al      | 514                    | 253.04   |                            |    |
|   | BH | 20   | 01 | 00 | 18 | 4 | 1           | 3               | 08/30/2001                    | CRAIN et al      | 514                    | 2        |                            |    |
|   | BI | 4  | 7  | 2  | 2  | 9 | 2           | 8               | 02/02/1998                    | BOSWELL et al    | 514                    | 282      |                            |    |
|   | BJ | 4  | 7  | 6  | 9  | 3 | 7           | 2               | 09/06/1988                    | KREEK et al      | 514                    | 282      |                            |    |
|   | BK | 3  | 8  | 4  | 5  | 7 | 7           | 0               | 11/05/1974                    | THEEUWES et al   | 128                    | 260      |                            |    |
|   | BL | 4  | 0  | 6  | 3  | 0 | 6           | 4               | 12/13/1977                    | SAUNDERS et al   | 219                    | 121      |                            |    |
|   | BM | 5  | 5  | 3  | 4  | 4 | 9           | 2               | 7/09/1996                     | ASTON et al.     | 514                    | 608      |                            |    |
|   | BN | 6  | 1  | 9  | 4  | 3 | 8           | 2               | 02/27/2001                    | CRAIN et al      | 514                    | 2        |                            |    |
| FOREIGN PATENT DOCUMENTS  |    |  |    |    |    |   |             |                 |                               |                  |                        |          |                            |    |
|   |    | DOCUMENT NUMBER  |    |    |    |   |             |                 | DATE                          | COUNTRY          | CLASS                  | SUBCLASS | TRANSLATION                |    |
|   |    |  |    |    |    |   |             |                 |                               |                  |                        |          | YES                        | NO |
| /ZF/  | BO | 0  | 1  | 8  | 5  | 1 | 5           | 0               | 11/15/2001                    | WO               | A61K                   | 31/00    |                            |    |
|   | BP | 0  | 0  | 6  | 7  | 7 | 3           | 9               | 11/16/2000                    | WO               | A61K                   | 31/00    |                            |    |
|   | BQ | 0  | 0  | 5  | 1  | 5 | 9           | 2               | 09/08/2000                    | WO               | A61K                   | 31/14    |                            |    |
|   | BR | 9  | 8  | 3  | 5  | 6 | 7           | 9               | 08/20/1998                    | WO               | A61K                   | 31/485   |                            |    |
|   | BS | 0  | 1  | 5  | 8  | 4 | 5           | 1               | 08/16/2001                    | WO(A1)           | A61K                   | 31/485   |                            |    |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |  |    |    |    |   |             |                 |                               |                  |                        |          |                            |    |
|   | BT | Abstract of FOSS et al., "Prevention of Apomorphine- or Cisplatin- induced emesis in the dog by combination of Methylnaltrexone and Morphine," Cancer Chemother. Pharmacol. (1998); 42(4): 287-91. |    |    |    |   |             |                 |                               |                  |                        |          |                            |    |
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| /ZF/  | CA | 5  | 6 | 0           | 4 | 2 | 6 | 0 | 02/18/1997                    | GUAY et al       | 514                    | 605      |                            |     |
|   | CB | 5  | 5 | 1           | 0 | 3 | 6 | 8 | 04/23/1996                    | LAU et al        | 514                    | 419      |                            |     |
|   | CC | 6  | 3 | 1           | 0 | 0 | 7 | 2 | 10/30/2001                    | SMITH et al      | 514                    | 282      |                            |     |
|   | CD | 6  | 7 | 6           | 5 | 0 | 1 | 0 | 07/20/2004                    | CRAIN et al      | 514                    | 282      |                            |     |
|   | CE | 6  | 2 | 7           | 7 | 3 | 8 | 4 | 08/21/2001                    | KAIKO et al      | 424                    | 400      |                            |     |
|   | CF | 5  | 4 | 0           | 9 | 9 | 4 | 4 | 04/25/1995                    | BLACK et al.     | 514                    | 359      |                            |     |
|   | CG | 5  | 1 | 3           | 0 | 3 | 1 | 1 | 07/14/1992                    | GUILLAUMET et al | 514                    | 234.2    |                            |     |
|   | CH | 5  | 5 | 2           | 1 | 2 | 1 | 3 | 05/28/1996                    | PRASIT et al     | 514                    | 443      |                            |     |
|   | CI | 5  | 4 | 3           | 6 | 2 | 6 | 5 | 07/25/1995                    | BLACK et al      | 514                    | 420      |                            |     |
|   | CJ | 5  | 6 | 3           | 9 | 7 | 8 | 0 | 06/17/1997                    | LAU et al        | 514                    | 419      |                            |     |
|   | CK | 5  | 6 | 0           | 4 | 2 | 5 | 3 | 02/18/1997                    | LAU et al        | 514                    | 415      |                            |     |
|   | CL | 5  | 5 | 9           | 3 | 9 | 9 | 4 | 01/14/1997                    | BATT et al       | 514                    | 252      |                            |     |
|   | CM | 5  | 5 | 3           | 6 | 7 | 5 | 2 | 07/16/1996                    | DUCHARME et al   | 514                    | 602      |                            |     |
|   | CN | 5  | 5 | 5           | 0 | 1 | 4 | 2 | 08/27/1996                    | DUCHARME et al   | 514                    | 365      |                            |     |
|   | CO |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
| FOREIGN PATENT DOCUMENTS  |    |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
|   |    | DOCUMENT NUMBER  |   |             |   |   |   |   | DATE                          | COUNTRY          | CLASS                  | SUBCLASS | TRANSLATION                |     |
|   |    |  |   |             |   |   |   |   |                               |                  |                        |          |                            | YES |
|   | CP |  |   |             |   |   |   |   |                               |                  |                        |          | NO                         |     |
|   | CQ |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
|   | CR |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
| /ZF/  | CS | MIAKOWSKI et al., "Inhibition of Spinal Opioid Analgesia by Supraspinal Administration of Selective Opioid Antagonists," Brain Research (1992), 30: 263-274. |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
|   | CT |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
|   | CU |  |   |             |   |   |   |   |                               |                  |                        |          |                            |     |
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| U.S. PATENT DOCUMENTS  |    |  |   |   |   |   |             |                               |            |                        |          |                            |    |
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| /ZF/   | DA | 4  | 0 | 8 | 8 | 8 | 6           | 4                             | 05/09/1978 | THEEUWES et al         | 219      | 121                        |    |
|  | DB | 4  | 2 | 9 | 3 | 5 | 3           | 9                             | 10/06/1981 | LUDWIG et al           | 429      | 19                         |    |
|  | DC | 4  | 9 | 5 | 7 | 6 | 8           | 1                             | 09/18/1990 | KLIMESCH et al         | 264      | 211.23                     |    |
|  | DD | 3  | 1 | 7 | 3 | 8 | 7           | 7                             | 03/16/1965 | JACKSON et al          | 252      | 138                        |    |
|  | DE | 6  | 2 | 2 | 8 | 8 | 6           | 3                             | 05/08/2001 | PALERMO et al          | 514      | 282                        |    |
|  | DF | 6  | 6 | 2 | 7 | 6 | 3           | 5                             | 09/30/2003 | PALERMO et al          | 514      | 282                        |    |
|  | DG | 6  | 7 | 1 | 6 | 4 | 4           | 9                             | 04/06/2004 | OSHLACK et al          | 424      | 449                        |    |
| V  | DH | 6  | 6 | 9 | 6 | 0 | 8           | 8                             | 02/24/2004 | OSHLACK et al          | 424      | 465                        |    |
|  | DI | 6  | 6 | 9 | 6 | 0 | 6           | 6                             | 02/24/2004 | KAIKO et al            | 424      | 400                        |    |
| FOREIGN PATENT DOCUMENTS   |    |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  |    | DOCUMENT NUMBER  |   |   |   |   |             | DATE                          | COUNTRY    | CLASS                  | SUBCLASS | TRANSLATION                |    |
|  |    |  |   |   |   |   |             |                               |            |                        |          | YES                        | NO |
|  | DJ |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DK |  |   |   |   |   |             |                               |            |                        |          |                            |    |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)   |    |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DL |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DM |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DN |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DO |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DP |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DQ |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DR |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DS |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DT |  |   |   |   |   |             |                               |            |                        |          |                            |    |
|  | DU |  |   |   |   |   |             |                               |            |                        |          |                            |    |
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